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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/519,728 03/03/00 WEINTRAUB

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020995 HM12/0705
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EXAMINER

LAZAR WESLEY E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/519,728

Applicant(s)
Weintraub

Examiner
Eliane Lazar-Wesley

Art Unit
1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 41, drawn to a mutant alpha subunit, classified in class 540, subclass 350.
 - II. Claims 13-25, and 57, 60, 63, 64, 66, drawn to a mutant TSH heterodimer, compositions and a kit, classified in class 530, subclass 397.
 - III. Claims 26-31, 39, and 58, 61, 62, 63, 64, 66, drawn to a mutant TSH heterodimer wherein at least the beta or the alpha subunit contains a substitution, compositions and a kit, classified in class 530, subclass 397.
 - IV. Claims 32-38, 40, 42, 59, 63, 64, 65, 66, drawn to a TSH analog wherein the subunits are covalently bound, classified in class 530, subclass 397.
 - V. Claim 43, drawn to a method of treating or preventing hypothyroidism by administering mutant TSH heterodimer, classified in class 514, subclass 8.
 - VI. Claim 44, drawn to a method of treating or preventing hypothyroidism by administering TSH analog, classified in class 514, subclass 8.
 - VII. Claims 45, 46, drawn to a method of treating thyroid cancer by administering mutant TSH heterodimer, classified in class 514, subclass 8.

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- VIII. Claim 47, drawn to a method of diagnosing thyroid cancer, by administering mutant TSH heterodimer, classified in class 514 subclass 8.
- IX. Claim 48, drawn to a method of diagnosing thyroid cancer, by administering mutant TSH, classified in class 514 subclass 8.
- X. Claim 49, drawn to a method of diagnosing thyroid cancer, by administering mutant TSH heterodimer, classified in class 514 subclass 8.
- XI. Claims 50, 51, drawn to a method of diagnosing thyroid cancer, by administering TSH analog, classified in class 514 subclass 8.
- XII. Claim 52, drawn to a method of diagnosing thyroid cancer, by administering TSH analog, classified in class 514 subclass 8.
- XIII. Claims 53, 54, drawn to a method of diagnosing or screening for disorder characterized by the presence of antibodies against TSH receptor, using TSH heterodimer, classified in class 435 subclass 7.1.
- XIV. Claims 55, 56, drawn to a method of diagnosing or screening for disorder characterized by the presence of antibodies against TSH receptor, using TSH analog, classified in class 435 subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I-IV are independent and distinct, as they differ structurally and functionally.

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The products of Inventions I-IV , and the methods of Inventions V-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the compositions can be practiced with other substances, and the products can be used to make antibodies.

The methods of Claims V-XIII are independent and distinct, as they use different reagents and method steps, and reach different goals.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different subject matter and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

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Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

July 02, 2001

ELW

**CHRISTINE J. SAUD
PRIMARY EXAMINER**

Christine J. Saud